



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFL-35

5171

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

Warning Letter

WL-CIN-6300-01

February 12, 2001

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Simon Weiner, President
Basik Swift & Determined
Dba Medicare Products
946 E. 131st Street
Cleveland, OH 44108

Dear Mr. Weiner,

During the period of January 2 - January 5, 2000 an investigator from our office documented that you had distributed products from two different customs entries (W86-0059736-0 and W86-0063822-2) without first having received a Notice of Release from FDA. This is a violation of 21 CFR 1.90 that requires the importer to hold the entry intact pending notification from FDA.

Failure to prevent future violations may result in regulatory action such as seizure, injunction or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported product meets all requirements of the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder.

Note also that the failure to hold future shipments will result in a claim for liquidated damages under the provisions of the entry bond.

Within 15 working days of the receipt of this letter, notify this office in writing of the specific steps you have taken to prevent the recurrence of this type of violation.

Your reply should be addressed to Food and Drug Administration, Attention Stephen J. Rabe, Compliance Officer.

Sincerely

Henry L. Fielden
District Director
Cincinnati District Office